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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,871	09/19/2003	Andrew H. Segal	11111/2003B	8447

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EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,871

Applicant(s)

SEGAL ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is a supplemental action intended to replace the Restriction Requirement mailed on August 19, 2004, in which claims 6-14 were omitted from the requirement.
2. The examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Emily Le in Art Unit 1648.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 5, and 15-68, drawn to fusion polypeptides comprising a first amino acid sequence comprising the carbohydrate binding domain of a C-type lectin (including collectins) and a second amino acid sequence comprising a ligand for a cell surface receptor, classified in class 424, subclass 192.1.
 - II. Claims 1-3 and 15-68, drawn to fusion polypeptides comprising a first amino acid sequence comprising the carbohydrate binding domain of a galectin and a second amino acid sequence comprising a ligand for a cell surface receptor, classified in class 424, subclass 192.1.
 - III. Claims 1-68, drawn to fusion polypeptides comprising a first amino acid sequence comprising a sequence that binds to a carbohydrate on a

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glycoprotein and a second amino acid sequence comprising a ligand for a cell surface receptor, classified in class 424, subclass 192.1.

For Group III above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-III, and, if Group III is elected, then election is also required to one of subgroups (C)- (G). These subgroups represent the claimed invention wherein the carbohydrate to which the first amino acid sequence binds is:

- (C) D-mannose,
- (D) D-glucose,
- (E) D-fucose,
- (F) L-fucose,
- (G) N-acetyl-beta-D-glucosamine, or
- (H) sialic acid (including hemagglutinin).

For each of Groups I-III above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-III, and one of inventions (1)- (6). The inventions of subgroups (1)-(6) represent the claimed invention, wherein the second amino acid sequence is for a ligand of a cell surface polypeptide, wherein the cell surface polypeptide is:

- (1) a cytokine receptor,
- (2) CD40,
- (3) an adhesion molecule,
- (4) a defensin receptor,
- (5) a heat shock protein receptor, or
- (6) a counterreceptor for a T-cell costimulatory molecule.

If the Applicant elects subgroup (1) above, the Applicant is further required to elect one of the following types of cytokine receptors:

- (a) GM-CSF receptors,
- (b) an interleukin receptor,
- (c) a chemokine receptor,
- (d) an interferon receptor,
- (e) a TNF-alpha receptor, or
- (f) a flt-3 receptor.

The inventions are distinct, each from the other because of the following reasons:

4. The inventions of Groups I-III, and the inventions of the different subgroups thereof, are unrelated. Inventions are unrelated if it can be shown that they are not

disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each have different carbohydrate binding domains, and different cell surface ligand domains. Thus, the different proteins would each have a different mode of operation and achieve a different effect. The inventions are therefore distinct.

Species Election

5. **Subgroups (2)-(6) and H above** are generic to a plurality of disclosed patentably distinct species.

The inventions of subgroups (2)-(6) have been described above. If the Applicant elects one of these groups, the Applicant is also required to elect an example of the indicated set of ligands from those disclosed in the application (if any are so disclosed).

The inventions of subgroup H comprise hemagglutinin (HA) proteins from different influenza virus. The disclosed species include the HA proteins of the influenza virus subtypes listed on (e.g.) page 9 of the application.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: **the inventions of each of subgroups (b)-(d) above** represent a generic group of inventions.

The inventions of **subgroup (b)** comprise fusion proteins wherein the second amino acid sequence is that of a ligand to an interleukin receptor. If the Applicant elected this group above, Applicant is additionally required to elect one of the species set forth in (e.g.) claim 31.

The inventions of **subgroup (c)** comprise fusion proteins wherein the second amino acid sequence is that of a ligand to a chemokine receptor. If the Applicant elected this group above, Applicant is additionally required to elect one of the species set forth in (e.g.) claims 41 or 42.

The inventions of **subgroup (d)** comprise fusion proteins wherein the second amino acid sequence is that of a ligand to an interferon receptor. If the Applicant elected this group above, Applicant is additionally required to elect one of the species set forth in (e.g.) claim 50.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 28, 36, and 47 are generic for the inventions of subgroups (b)-(d) respectively.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

7. Because these inventions are distinct for the reasons given above, and because the search required for any one of the claimed inventions requires a search not required for the other inventions, restriction for examination purposes as indicated is proper.

8. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Claim 1 is considered a linking claim for certain inventions falling within its scope.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648



E. Le